

potential route of human disease transmission and to understand the most current community barriers to reaching that final goal.

Persistence of Ebola Virus (EBOV) in Body Fluids of EVD Survivors in Sierra Leone is the first systematic examination of the post-recovery persistence of EBOV and the risks of transmission from a cohort of convalescent Ebola survivors during close or intimate contact. It is important to fully understand how long the virus stays active in body fluids other than blood in order to target and refine public health interventions to arrest the ongoing spread of disease.

The research study is comprised of three modules based on the body fluids to be studied: A pilot module of adult males (semen) and two full modules: Module A of adult men and women repeating collections and questionnaires every two weeks (semen, vaginal secretions, and saliva, tears, sweat, urine, rectal swab), and Module B of lactating adult women repeating

collections and questionnaires every three days (sweat and breast milk).

Participants for each module will be recruited by trained study staff from Ebola treatment units (ETUs) and survivor registries. Participants will be followed up at study sites in government hospitals.

Specimens will be tested for EBOV ribonucleic acid (RNA) by reverse transcription polymerase chain reaction test (RT-PCR) in Sierra Leone at the CDC laboratory facility in Bo. All positive RT-PCR samples will be sent to CDC Atlanta for virus isolation. Each body fluid will be collected until two negative RT-PCR results are obtained. Participants will be followed until all their studied body fluids are negative. They will receive tokens of appreciation for their participation at the initial visit and again at every subsequent follow-up visit [e.g., 120,000 Leones (approximately \$28 US dollars) and a supply of condoms]. For Module A, men and women will be recruited in equal numbers for this study until more information on gender effects of viral

persistence is available. A trained study data manager will collect test results for all participants in a laboratory results form.

Results and analyses are needed to update relevant counseling messages and recommendations from the Sierra Leone Ministry of Health, World Health Organization, and CDC. The study will provide the most current information that is critical to the development of public health measures, such as recommendations about sexual activity, breastfeeding, and other routine activities and approaches to evaluation of survivors to determine whether they can safely resume sexual activity. These approaches in turn are expected to reduce the risk of Ebola resurgence and mitigate stigma for thousands of survivors. The information is likewise critical to reducing the risk that Ebola would be introduced in a location that has not previously been affected.

The total burden hours requested for the research study in Sierra Leone is 1,836 hours. There are no costs to respondents other than their time.

#### ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	No. of respondents	No. of responses per respondent	Average burden per response (hours)
Data manager .....	Intake Form .....	1	550	20/60
Pilot participants .....	Survivor Questionnaire .....	100	1	30/60
Pilot participants .....	Survivor Follow-up Questionnaire .....	100	5	15/60
Pilot participants .....	3 & 6 Month Follow up Questionnaire .....	100	2	15/60
Main study male participants .....	Survivor Questionnaire .....	120	1	30/60
Main study male participants .....	Survivor Follow-up Questionnaire .....	120	12	15/60
Main study male participants .....	3 & 6 Month Follow up Questionnaire .....	120	2	15/60
Main study female participants .....	Survivor Questionnaire .....	120	1	30/60
Main study female participants .....	Survivor Follow-up Questionnaire .....	120	4	15/60
Main study female participants .....	3 & 6 Month Follow up Questionnaire .....	120	2	15/60
Data manager .....	Laboratory Results Form .....	1	4,250	10/60

#### Leroy A. Richardson,

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### National Institutes of Health

##### National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel, R13 Conference Grant Application Review.

*Date:* April 28, 2016.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* William J. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892-7924, 301-435-0725, [johnsonwj@nhlbi.nih.gov](mailto:johnsonwj@nhlbi.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 30, 2016.

**Anna Snouffer,**

Deputy Director, Office of Federal Advisory Committee Policy.

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